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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/780,159

02/17/2004

Joseph DeMco

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KENSEY NASH CORPORATION
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EXAMINER

CHEN, VIVIAN

ART UNIT

PAPER NUMBER

1794

MAIL DATE

DELIVERY MODE

11/14/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

10/780,159

Applicant(s)

DEMEO ET AL.

Examiner

Vivian Chen

Art Unit

1794

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 26 October 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: 1-4, 23, 24, 28-31 and 33-40.
Claim(s) withdrawn from consideration: 22 and 41.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
see Detailed Advisory Action.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____.
13. ☐ Other: _____.

Vivian Chen
Primary Examiner
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DETAILED ADVISORY ACTION

1. Claims 5-21, 25-27, 32 have been cancelled by Applicant.

Claim Rejections - 35 USC § 103

1. Claims 1-4, 23-24, 28-31, 33-40 remain rejected under 35 U.S.C. 103(a) as being unpatentable over NAKAMURA ET AL (US 2003/0146541), in view of BURKHEAD ET AL (US 2001/0004693), as stated in the previous Office Actions

Response to Arguments

2. Applicant's arguments filed 10/26/2007 have been fully considered but they are not persuasive.

(A) Applicant argues that NAKAMURA fails to teach the claimed invention because the reshaped head of the devices disclosed in the reference would not have molecular orientation substantially in the direction of the longitudinal axis of the device. However, the present claims merely state that the longitudinal axis is “*an* axis of said molecular orientation” and thereby do not require that the entire device (both head and shank) must have the same identical single axis of molecular orientation (i.e., along the longitudinal direction). Therefore, the fact that the direction of the molecular orientation in the reshaped head portion of the NAKAMURA devices may differ from the direction of molecular orientation in other portions of the device is irrelevant. As long as a portion of the molecular orientation lies along a longitudinal axis of the device, the limitations of the present claims are met.

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(B) Applicant argues that the phrase “a longitudinal axis” inherently references to a single or common longitudinal axis. However, the Examiner is not persuaded because the term “a longitudinal axis” by itself does not inherently require that the longitudinal axis of the head and the longitudinal axis of the shank portion be the one and the same. The phrase “arranged on a longitudinal axis” may be reasonably interpreted as simply specifying that each portion has a distinguishable “lengthwise” direction.

Furthermore, it is noted that the features upon which applicant relies (i.e., a single longitudinal axis) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

(C) Applicant argues that BURKHEAD fails to disclose or suggest the claimed invention because the reshaped head of the devices disclosed in the reference would not have molecular orientation substantially in the direction of the single longitudinal axis of the device. However, the present claims merely state that the longitudinal axis is “*an* axis of said molecular orientation” and thereby do not require that the entire device (both head and shank) must have the same identical single axis of molecular orientation (i.e., along the longitudinal direction). Therefore, the fact that the direction of the molecular orientation in the reshaped head portion of the BURKHEAD devices may differ from the direction of molecular orientation in other portions of the device is irrelevant.

(D) Applicant argues that BURKHEAD fails to disclose a device wherein the head and the shank are arranged on a longitudinal axis. As an initial matter BURKHEAD is primarily relied upon to illustrate that it is well known in the art to form implantable articles with different

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degrees of orientation in different regions. With respect to Applicant's argument that the head portion of BURKHEAD is not "arranged on" the longitudinal axis, while the head portion *contains* an element which deviates from the overall longitudinal axis of the device, that does not obviate the fact that the head portion as a whole is situated at the tip of the shank, and therefore may be reasonably considered to be "arranged on" the overall longitudinal axis of the device (i.e., placed in a position in the lengthwise direction). Accepting Applicant's interpretation of "arranged on a longitudinal axis" would mean that absolutely no part or element of the head portion can deviate from or have an axis different from the longitudinal axis, thereby excluding any device in which the head portion has a diameter is greater than its shank diameter, because according to Applicant's particular interpretation, such head portions are not arranged on a longitudinal axis with the shank portion. For example, Applicant's interpretation would appear to preclude devices having widened head portions as denoted by reference number 6 in Applicant's own Figures.

Conclusion

1. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vivian Chen whose telephone number is (571) 272-1506. The examiner can normally be reached on Monday through Thursday from 8:30 AM to 6 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carol Chaney, can be reached on (571) 272-1284. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

The General Information telephone number for Technology Center 1700 is (571) 272-1700.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

November 9, 2007



Vivian Chen
Primary Examiner
Art Unit 1794